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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,314	06/29/2000	Richard Fike	0942.4290005/RWE/BJD	1340

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Sterne Kessler Goldstein & Fox PLLC
Suite 600
1100 New York Avenue NW
Washington, DC 20005-3934

EXAMINER
FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 02/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/606,314	Applicant(s) Fike et al.
	Examiner Michele Flood	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 13, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *27, 29-37, 39-55, 60-72, and 92-99* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *27, 29-37, 39-55, 60-72, and 92-99* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendments filed on December 13, 2001. Acknowledgment is made of newly submitted claims 92-99.

Election/Restriction

Applicant's election with traverse of Group I and the species election of making a nutritive medium powder (i.e., agglomeration as the method of making a nutritive medium powder, water as the solvent, and dry powder medium as the starting material for making of the nutritive medium powder) in Paper No. 11 is acknowledged. The traversal is on the ground that the search for one group would include a search for another group because the components of media and supplements of the different inventions overlap. This is not found persuasive because the different inventions of Groups I-III and V are directed to four different products comprising different ingredients, and thus are different inventions; and the invention of Group IV is directed to a method of using a nutritive medium powder which can be practiced with four different materially different products, as evidenced by the claims themselves. The Office obliges answering Applicant's election of Group I with traverse, however, the Office's answer to Applicant's arguments are deemed moot in view of Applicant's substantial amendment of the claims which provide for yet other inventions.

Upon further review, Claims 31-35 have been found to be directed to an another invention, wherein the claims are drawn to an automatically pH-adjusting nutritive medium powder. Newly submitted Claims 96-99 are found to be directed to an additional invention, as well. Thus, a new restriction requirement is deemed necessary as set forth below.

I. Claims 27, 36, 37, 39, 44-47, 70, 72, 92-95, drawn to nutritive medium powders prepared by agglomerating a dry powder eukaryotic nutritive medium with a solvent, classified in class 435, subclass 325+, for example.

II. Claims 29, 36, 41, 70 and 72, drawn to a nutritive medium powder prepared by spray-drying a liquid medium to form a powder, then agglomerating said powder with a solvent, classified in class 435, subclass 243, for example.

III. Claims 30, 36, 70 and 72, drawn to a nutritive medium powder prepared by: (a) forming a powder by (i) agglomerating a dry powder medium with a solvent, or (ii) spray-drying a liquid nutritive medium; and (b) agglomerating an acid or base into said powder, classified in class 435, subclass 243+, for example.

IV. Claims 31-36, 70 and 72, drawn to an automatically pH-adjusting nutritive medium powder, classified in class 34, subclass 372, for example.

V. Claim 40, drawn to a nutritive medium subgroup powder prepared by spray-drying a liquid nutritive medium subgroup, classified in class 435, subclass 325+ or class 435, subclass 410+, for example.

VI. Claim 41, drawn to a nutritive subgroup medium powder prepared by spray-drying a liquid nutritive medium subgroup to form a powder, then agglomerating the powder with a solvent, classified in class 435, subclass 325+ or class 435, subclass 410+, for example.

VII. Claim 42, drawn to a buffer powder prepared by agglomerating a dry powder buffer with a solvent, classified in class 430, subclass 492, for example.

VIII. Claim 43, drawn to a buffer powder prepared by spray-drying a liquid buffer solution, classified in class 435, subclass 486, for example.

IX. Claims 48-55, drawn to a method of culturing a cell comprising reconstituting the nutritive medium powder of any one of claims 27 and 29-31 with a solvent to form a liquid solution and contacting the cell with said liquid solution under conditions favoring the cultivation of the cell, classified in class 435, subclass 254.1, for example.

X. Claims 60-69, drawn to a sterile nutritive medium supplement powder prepared by (a) obtaining a nutritive medium supplement powder to be sterilized; and (b) sterilizing said powder by irradiation of said powder with gamma rays until said powder is rendered sterile, classified in class 435, subclass 173.1, for example.

XI. Claim 71, drawn to a kit for use in the cultivation of a cell, said kit comprising one or more containers wherein a first container contains a powder, and one or

more additional containers containing one or more cells, classified in class 435, subclass 810, for example.

XII. Claims 96-99, drawn to a liquid medium, classified in class 435, subclass 383, for example.

1. The inventions are distinct, each from the other because of the following reasons: Inventions I-VIII and X-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, all have different end products, and thus are distinct inventions.

The several products above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. For instance, the invention of Group I differs from each of the inventions of Groups II-VIII and X-XII because the claimed product is made by agglomerating a dry powder medium with a solvent, whereas the remaining groups do not necessarily require the instantly claimed process of making the product. The invention of Group II differs from each of the inventions of Groups I, III-VIII and X-XII because the claimed product is made by spray-drying a liquid medium to form a powder, then agglomerating said powder with a solvent, whereas the remaining groups do not necessarilyy require the instantly claimed process of making the product. The invention of Group III differs from each of the inventions of Groups I-II, IV-VIII

and X-XII because the claimed product is made by either agglomerating a dry powder medium with a solvent or spray-drying a liquid nutritive medium; and then agglomerating an acid or base into the prepared powders, whereas the remaining groups do not necessarily require the instantly claimed process of making the product and do not require the claimed ingredients in the making of the product. The invention of Group IV differs from each of the inventions of Groups I-III, V-VIII and X-XII because the claimed product is directed to an automatically pH-adjusting nutritive medium powder, which does not require any of the claimed methods of making the other products, i.e. agglomerating or spray-drying. The invention of Group V differs from each of the inventions of Groups I-IV and X-XII because the claimed product is made by spray-drying a liquid nutritive medium subgroup, whereas the remaining groups do not necessarily require the instantly claimed process of making the claimed product and do not necessarily require the same ingredients. The invention of Group VI differs from each of the inventions of Groups I-V and X-XII because the claimed product is made by spray-drying a liquid nutritive medium subgroup to form a powder, then agglomerating the powder with a solvent, whereas the remaining groups do not necessarily require the process steps for making the claimed product. The invention of Group VII differs from each of the inventions of Groups I-VI and X-XII because the claimed product is made by agglomerating a dry powder buffer with a solvent, whereas the remaining groups do not necessarily require the instantly claimed ingredients, and do not necessarily require the process steps for making the claimed product. The invention of Group VIII differs from each of the inventions of Groups I-VII and X-XII because the claimed product is made by spray-drying a

liquid buffer solution, whereas the remaining groups do not necessarily require the instantly claimed ingredients, and do not necessarily require the process steps for making the claimed product. The invention of Group X differs from each of the inventions of Groups I-VIII and XI-XII because the claimed product is made by process steps not required by any of the other claimed products. The invention of Group XI differs from each of the inventions of Groups I-VIII and XII because the claimed product requires other ingredients not required by the remaining groups. The invention of Group XII differs from each of the inventions of Groups I-VIII and X-XI because the claimed product requires other ingredients not required by the remaining groups; moreover, the claimed product is no longer deemed a powder once it is dissolved in a solvent, but is liquid medium wherein the composition of the matter is not clearly delineated or defined, whereas the remaining groups require at least a powder product.

Thus, the search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

2. Inventions I-IV and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case, the process can be practiced with four different materially different products, as evidenced by the claims themselves.

3. Because these inventions are distinct for the reasons given above and the search required for one Group is not required for another Group, restriction for examination purposes as indicated is proper.

4. With regard to Claim 30, this application contains a claim directed to the following patentably distinct species of the claimed invention: a nutritive medium powder prepared by agglomerating a dry powder medium with a solvent, then agglomerating an acid or base into the agglomerated powder and a nutritive medium powder prepared by spray-drying a liquid nutritive medium, and the agglomerating an acid or vase into the spray-dried powder.

If Applicant elects Group III set forth above, Applicant is **also** required under 35 U.S.C. 121 to elect a single disclosed species of method of making a nutritive medium powder, that is either agglomerating a dry powder medium with a solvent, then agglomerating an acid or base into the agglomerated powder **or** spray-drying a liquid nutritive medium, then agglomerating an acid or base into the spray-dried powder, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. A telephone call was made to Brian J. Del Buono on February 7, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Michael Wityshyn whose telephone number is (703) 308-4743.

MCF

February 15, 2002

CHRISTOPHER R. TATE
PRIMARY EXAMINER